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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/120,030	07/21/1998	BETH P GOLDSTEIN	7732-022-27	1743

7590 05/27/2003

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EXAMINER

BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 05/27/2003

29

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/120,030

Applicant(s)

Goldstein et al.

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 20, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4, 5, 28, 32, 35, 41-51, and 56-60 is/are pending in the application.
- 4a) Of the above, claim(s) 28 and 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4, 5, 32, 41-51, and 56-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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DETAILED ACTION

Status of Claims

1. Amendment filed 03/20/2003 is acknowledged. Claims 52-55 are canceled. Claims 4,5,28,32,35,41-51,56-60 are pending. Claims 4, 41-47, 60 are amended. Claims 28,35 remain withdrawn from consideration as being drawn to a non-elected groups. Cancellation of claims 28,35 is repeatedly requested.

Claims 4,5,32,41-51,56-60 are under examination.

2. Applicant's arguments have been fully considered and they are deemed to be persuasive-in-part. The following rejections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112, first paragraph.

3. Claims 4,5,32,44-47,56-59 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claims 4,5,44-47 introduce new matter by using open-ended dosage range with no lower limit. Note that the widest range disclosed in the specification is 0.5-200 mg/kg/day

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(p. 10). There is no disclosure in the specification of the dosages below this range ; however, such lower dosage are within the scope of the amended claims.

Claim Rejections - 35 USC § 103

4. Claims 4,5,32,41-51,56-60 are rejected are rejected under 35 U.S.C. 103(a) as obvious over Zygmunt, and Goldberg and Stark, and further in view of Oldham. The rejection is maintained for the reasons of record as set forth for claims 4,5,32,41-60, and further in view of the following.

In regard to Zygmunt reference, applicant refers to a single example (on page 319) of this extensive review article summarizing plurality of studies. Within the same page of the review, one can allocate plurality of references to other studies where lysostaphin was administered many hours (rather than one hour) of infection. In regard to dosages, the reference describes intravenous administration of lysostaphin in doses within the instantly claimed range. See Table 4, p. 320, and Figure 7, p. 319. As for multiple administration, it would be obvious to an artisan to continue administration until achieving desirable effect.

As for Goldberg reference, applicant does not provide explanations for way of compilation and recalculating data of the reference: neither Table I or II, or derived

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range of 31.6 to 186 mg/kg/day are present in the reference. Rather, Table I demonstrates treatment of dogs with staphylococcal endocarditis (which simulates established staphylococcal infection in man, see p. 46, first paragraph) with multiple doses of lysostaphin, wherein within the instantly claimed range of dosages. See, e.g., dogs #4-7, 10,13 for which the dosage is clearly less than 30 mg/kg/day. Note further, that lysostaphin was administered in the amount of 3-30 ml of 30 mg/ml solution (see *Treatment Regiments* in Material and Methods), which, again would yield dosages within the claimed range. As for the outcome of the treatment, instant claims are drawn to "treatment", not complete healing, which does not exclude incomplete treatment or relapse episodes.

Further, in regard to "low" dosages to which the instant claims are now limited, the issue that was not addressed yet, but will be brought up if necessary, is that the claims are presented in open "comprising" language which does not exclude use of another antibiotic (claims 32, 58 expressly state it), and synergism of lysostaphin with other antibiotics is well known (as discussed in detail in co-pending applications) which motivates an artisan to reduce dosage of lysostaphin.

As for discussion of other references used in the rejection, Examiner maintains their use for the reasons set forth in the rejection.

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As for demonstration of "objective evidence for non-obviousness" presented on pages 9-10 of response, it is not clear what presents an unexpected result. See, e.g. results of treatment of endocarditis discussed in Goldberg.

5. Claims 32,42,43,46,47,50,51,54,55 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Zygmunt, and Goldberg and Stark, and Oldham as applied above, and further in view of Dixon. The rejection is maintained for the reasons of record.

Applicant refers to arguments presented in relation to claims 4,5; this arguments were addressed above.

Conclusion.

6. No claims are allowed

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

